

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

APOTEX, INC.,

Plaintiff,

v.

CEPHALON, INC., *et al.*

Defendants.

Civil Action No. 2:06-cv-2768-MSG

**APOTEX’S MEMORANDUM OF LAW IN SUPPORT OF APOTEX’S MOTION FOR
ENTRY OF PARTIAL, FINAL JUDGMENT ON COUNTS I, II, III AND V OF
APOTEX’S SECOND AMENDED COMPLAINT**

Previously, the Court dismissed the invalidity claim on the '346 patent (Count IV) (*see* D.I. 458) and entered summary judgment of non-infringement of the '346 patent (Count V) (*see* D.I. 435) of Apotex's Second Amended Complaint (“Complaint”) (*see* D.I. 195). On October 31, 2011, the Court found the claims of the ‘516 patent unenforceable due to Cephalon’s inequitable conduct and invalid on a number of grounds. (*See* D.I. 513.) In light of these rulings, the Court entered judgment on Counts I and II, respectively, of the Complaint in Apotex’s favor. (*See* D.I. 514.) The only other patent-related count pending is the infringement of the ‘516 patent (Count III), which the Court is currently considering after the July 2011 bench trial and related briefing. Apotex respectfully requests that when the Court makes its determination as to the non-infringement count regarding the ‘516 patent, it issue a judgment under Fed. R. Civ. P. 54(b) as to all of the decided patent claims for both the RE ‘516 and ‘346 patents, i.e. Counts I, II, III, and V.

An entry under Fed. R. Civ. P. 54(b) is necessary because Apotex needs a final decision (from which no appeal as a matter of right can be taken) to trigger the 180-day exclusivity period of the four Generic Defendants. Because Apotex's Complaint has antitrust and other unfair competition counts, if the patent claims are not certified under Rule 54(b), Apotex would have to wait until the conclusion of the *antitrust* trial, and the appeals of both the antitrust and patent claims, before it could receive a final non-appealable decision to trigger the exclusivity period, which blocks Apotex from final FDA approval of its modafinil ANDA.¹

The Court did not certify the '346 patent claims under Rule 54(b) on April 27, 2011 (*see* D.I. 458, noting that several of the *Berkeley*² factors weighed in Apotex's favor), because it was waiting to resolve the '516 patent claims, with the intention of certifying them together. Cephalon agreed that an appeal regarding the '346 patent should be part of a single appeal with the '516 patent. (*See* D.I. 441).³ Apotex requests that once the final pending patent count on infringement of the '516 patent (Count III) is decided, all the patent-related counts be certified under Rule 54(b), and makes this request now (with Count III still pending) to save time – Apotex is currently held out of the modafinil market and its ability to sell product and make money is delayed every day this case remains pending.

ARGUMENT

Rule 54(b) permits a district court to sever one or more individual claims that have been fully resolved. Rule 54(b) acknowledges the policy that in multiple claim actions, “some final

¹ Apotex has no intention to appeal any of the patent count rulings that have been decided to date (i.e. Counts I, II, and V). If Cephalon does not appeal these rulings, then this Court's orders in D.I. 435 and 514 would, in fact, trigger the 180 day exclusivity of the first-filing generic companies.

² *Berkeley Inv. Group, Ltd. v. Colkitt*, 259 F.3d 135, 144-45 (3d Cir. 2001).

³ Apotex sought Cephalon's agreement in bringing this current FRCP 54(b) motion. Cephalon did not agree and may oppose this motion.

decisions, on less than all of the claims, should be appealable without waiting for a final decision on all of the claims.” *W.L. Gore & Assoc. v. International Medical Prosthetics Research Assoc.*, 975 F.2d 858, 861 (Fed. Cir. 1992). In deciding whether to certify a judgment under Rule 54(b), a district court must (1) “determine whether the judgment is final in the sense that it is ‘an ultimate disposition of an individual claim entered in the course of a multiple claims action’”; and (2) “determine ‘whether any just reason for delay exists.’” *Medrad, Inc. v. Tyco Healthcare Group LP*, No. 01-CV-1997, 2005 U.S. Dist. LEXIS 40353, at *1 (W.D.P.A. Dec. 19, 2005) (quoting *Curtiss-Wright Corp. v. Gen. Elec. Co.*, 446 U.S. 1, 7, 8) (1980)) (entering partial final judgment as to patent claims).

While the Supreme Court and the Third Circuit⁴ both agree that Rule 54(b) judgments should not be entered routinely or as a courtesy or accommodation to counsel,⁵ they should be entered on an express determination that there is no just reason for delay. *See Reiter v. Cooper*, 507 U.S. 258, 265 (1993). For instance, in patent cases, Rule 54(b) has often been employed in situations similar to this case where the patent claims are adjudicated but antitrust claims remain. *See e.g., Tyco Healthcare Group LP v. Mut. Pharm. Co.*, 407 Fed. Appx. 481, 482 (Fed. Cir. 2011) (finding a motion for final judgment pursuant to Rule 54(b) appropriate in a Hatch-Waxman case where all patent infringement claims were adjudicated while antitrust and inequitable conduct claims remained pending); *Purdue Pharma L.P. v. Endo Pharms., Inc.*, 438 F.3d 1123, 1127-1128 (Fed. Cir. 2006) (permitting a final judgment under Rule 54(b) where all bifurcated patent claims were adjudicated but antitrust and unfair trade claims remained pending).

⁴ Even though this appeal will go to the Federal Circuit, Third Circuit law applies to the Rule 54(b) determination.

⁵ *See e.g., Panichella v. Pa. R.R. Co.*, 252 F.2d 452, 455 (3d Cir. 1958); *Curtiss-Wright Corp. v. Gen. Elec. Co.*, 446 U.S. 1, 10 (1980); *Gerardi v. Pelullo*, 16 F.3d 1363, 1372 (3d Cir. 1994).

In determining whether to grant a motion under Rule 54(b), the Third Circuit⁶ has identified five factors relevant to the question of whether to enter partial final judgment: (1) the relationship between the adjudicated and unadjudicated claims; (2) the possibility that the need for review might or might not be mooted by future developments in the district court; (3) the possibility that the reviewing court might be obliged to consider the same issue a second time; (4) the presence or absence of a claim or counterclaim that could result in setoff against the judgment sought to be made final;⁷ and (5) miscellaneous factors such as delay, economic and solvency considerations, shortening the time of trial, frivolity of competing claims, expense, etc. Courts should also “take into account judicial administrative interests as well as the equities involved” in making these determinations. *Curtiss-Wright*, 446 U.S. at 8. Here, application of the factors warrants entry of the requested Rule 54(b) judgment.

Factor 1: Relationship between adjudicated and unadjudicated claims

The adjudicated claims focus on the '516 and '346 patents under patent law while the remaining counts are for antitrust and other claims under different laws. *See Medrad*, 2005 U.S. Dist. LEXIS at *6-7. (“We conclude that the resolved patent claims and the pending antitrust claim are factually separable.”).

To the extent there is an overlap with the antitrust claims, the Court’s decisions on the ‘516 and ‘346 patents are law of the case and binding, so there is no risk of re-litigating the same issues. *See In Re Innotron Diagnostics*, 800 F. 2d 1077 (Fed Cir 1986). In *Innotron*, the district court had separated the antitrust claims from the patent claims. *Innotron*, 800 F 2d at 1079. The Federal Circuit confirmed that this was all one lawsuit, and that the separation of the patent from

⁶ *See e.g., Berkeley*, 259 F.3d at 144-45; *Allis-Chalmers Corp. v. Phila. Elec. Co.*, 521 F.2d 360, 364 (3d Cir. 1975).

⁷ The fourth factor is not applicable to this case because Cephalon’s only counterclaim is for infringement of the ‘516 patent. As such, it will not be addressed.

the antitrust claims was appropriate. According to the court, "...economy is served because in the trial of the patent issues the validity of the patent and Innotron's affirmative defenses will become law of the case and thus removed from trial on the original antitrust issues.." *Id.* at 1085. Further, if the antitrust complainant (Innotron) prevails on the patent issues at the patent trial, then all it need try in the antitrust trial are the "different issues of relevant market, predatory intent, market dominance, and (perhaps) guilty knowledge." *Id.* at 1086, fn 17; *Kimberly Clark Worldwide Inc v First Quality Baby Products LLC* , 2011 WL 1627052, at *2 (M.D. Pa. April 29, 2011) ("resolution of the patent disputes would become the law of the case, and thus eliminate or reduce some of the proof that would be necessary at trial on the [antitrust] counterclaims.") (citing *Official Comm. of Unsecured Creditors v Shapiro* , 190 F.R.D. 352, 354 (E.D. Pa. 2000).

Factor 2: Whether need for review might or might not be mooted

Apotex is not aware of any future development in the antitrust case that would moot the patent case. No matter what happens in the antitrust claims, Apotex's counts on the patents would need to be resolved to allow for it to trigger the 180-day exclusivity period and/or enter the market without risk of an infringement claim. For this reason, the second factor favors the entry of final judgment.

Factor 3: Whether reviewing court may consider the same issue twice

Similarly, there is no danger of the Federal Circuit being obliged to consider the patent issues of the adjudicated claims a second time because upon appeal the patent issues would be fully and finally determined, and therefore not at issue in the antitrust case. *See supra*, at Factor 1 (discussing law of the case doctrine). This factor thus favors entry of final judgment.

Factor 5: Miscellaneous factors

Finally, the miscellaneous criteria of the fifth factor strongly favor granting the requested Rule 54(b) judgment so that Apotex can obtain a final judgment on the patents to allow it to enter

the market before patent expiry. *See Curtiss-Wright*, 446 U.S. at 8 (courts should examine the “equities involved” in determining whether to enter judgment under Rule 54(b)). FDA approval of Apotex’s ANDA product depends on Apotex obtaining **final** judgments against the patents in order to trigger the 180-day exclusivity period. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Right now, Apotex is being held out of the market only by a patent that Cephalon fraudulently procured through inequitable conduct, while Cephalon reaps monopolistic profits. It would not be equitable to allow the status quo to remain any longer. This factor overwhelmingly supports entrance of a 54(b) judgment on the patent claims.

CONCLUSION

For all of the foregoing reasons, Apotex respectfully requests that this Court enter its decision on Counts I-III and V of Apotex’s Complaint as a final judgment under Federal Rule of Civil Procedure 54(b) by making the requisite findings that there is no just reason for delay in entering final judgment for potential appeal on these patent claims.

Respectfully submitted,

Dated: November 11, 2011

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CERTIFICATE OF SERVICE

I certify that on November 11, 2011, a copy of APOTEX'S MEMORANDUM OF LAW IN SUPPORT OF APOTEX'S MOTION FOR ENTRY OF PARTIAL, FINAL JUDGMENT ON COUNTS I, II, III AND V OF APOTEX'S SECOND AMENDED COMPLAINT was served via the Court's ECF system.

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